

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

_____	)	
KRISTIN DICROCE, individually and	)	
on behalf of all persons similarly	)	
situated,	)	
	)	
Plaintiff,	)	
	)	Civil Action
v.	)	No. 21-11660-PBS
	)	
MCNEIL NUTRITIONALS, LLC, and	)	
JOHNSON & JOHNSON CONSUMER, INC.,	)	
	)	
Defendants.	)	
_____	)	

**MEMORANDUM AND ORDER**

November 10, 2022

Saris, D.J.

**INTRODUCTION**

This putative class action returns to the court on Defendants McNeil Nutritionals, LLC ("McNeil") and Johnson and Johnson Consumer, Inc.'s ("J&J") motion to dismiss Plaintiff Kristin DiCrocce's Amended Complaint. DiCrocce alleges that Defendants unlawfully and misleadingly labeled their product Lactaid in violation of Massachusetts General Laws Chapter 93A and Chapter 266, Section 91. Defendants' motion argues that DiCrocce lacks standing and that the Amended Complaint fails to plead facts in support of each cause of action and is preempted. After hearing, the Court **ALLOWS** Defendants' motion to dismiss.

## **BACKGROUND**

### **I. The Amended Complaint**

The Amended Complaint challenges certain statements on the packaging of Lactaid, which Defendants market as a dietary supplement to assist with the digestion of dairy products. The core substantive allegation is that despite advertising Lactaid as a dietary supplement and not a drug, Defendants make statements on Lactaid labels suggesting that it is effective to treat a disease in violation of the Food, Drug, and Cosmetic Act ("FDCA") and Food & Drug Administration ("FDA") regulations. Thus, per DiCroce, the statements are materially misleading in violation of state law. DiCroce takes issue with the following statements found on labels for Lactaid's Fast Act Chewables, Fast Act Caplets, and Original Strength Caplets:

- "For the Prevention of Gas • Bloating • Diarrhea associated with digesting dairy."
- "Enjoy Dairy Again!"
- By taking Lactaid, "nothing can stop you from eating the foods you love. Our delicious vanilla chewables should be taken with your first bite of dairy, so that milk doesn't mess with you."
- "Don't let that annoying lactose get in the way of eating. LACTAID® Fast Act Caplets make dairy easier to digest so you can enjoy your favorite foods anytime, anywhere."
- "Experience the Total Joy of Dairy."
- "It's easier than ever to manage your lactose intolerance. Take up to three caplets with your first sip or bite of dairy to ensure that milk doesn't mess

with you. LACTAID® Original Strength Caplets lets you enjoy dairy anytime, anywhere."

Dkt. 45-1; Dkt. 45-2; Dkt. 45-3.

The Amended Complaint asserts that this labeling is false and misleading and therefore that the Lactaid products are misbranded. Specifically, a statement about a dietary supplement "may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases." 21 U.S.C. § 343(r)(6). And the label of any food or drug is misleading if it omits facts that are material either "in light of other representations made or suggested" or "with respect to consequences which may result from use of the article under (i) [t]he conditions prescribed in such labelling or (ii) such conditions of use as are customary or usual." 21 C.F.R. § 1.21(a). According to DiCroce, the above statements portray Lactaid as capable of diagnosing, preventing, treating, curing, or mitigating lactose intolerance, a disease. Thus, McNeil and J&J are effecting an "end-run" around FDA requirements by marketing Lactaid as a drug without obtaining FDA approval. Dkt. 45 ¶ 24.

Each of the Lactaid products' labels also contain disclaimers that DiCroce alleges compound the consumer confusion. First, after describing Lactaid as preventing gas, bloating, and diarrhea associated with digesting dairy, the labels add, "THIS STATEMENT HAS NOT BEEN EVALUATED BY THE FOOD & DRUG ADMINISTRATION." Dkt. 45-1; Dkt. 45-2; Dkt. 45-3. According to DiCroce, this warning is materially misleading because it suggests that FDA evaluation is

not required even though Lactaid's packaging makes disease claims. Thus, FDA evaluation and approval as a drug is required under the prevailing regulations. Second, the labels caution that "THIS PRODUCT IS NOT INTENDED TO DIAGNOSE, TREAT, CURE OR PREVENT ANY DISEASE." Id. The Amended Complaint alleges this disclaimer, too, is misleading because it contradicts other statements on Lactaid packaging implying that Lactaid is intended to treat symptoms of the disease of lactose intolerance. Notably, the packages also proclaim that Lactaid "is a dietary supplement, **NOT A DRUG**, and may be used by adults and children 4 years old and over. May be used every time you eat food containing dairy every meal, every snack, every day." Id.<sup>1</sup>

DiCroce alleges that she purchased Lactaid products many times over the past four years based on the alleged misstatements on the products' labels, and that had they been properly labeled, she would not have been misled by the claims. She maintains that if the products had been labeled correctly, she either would not have purchased Lactaid or would only have been willing to purchase Lactaid for a lower price. She adds that she "would have been able to compare the Lactaid Supplements to other lactose supplements that did not make illegal disease claims and see that

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<sup>1</sup> Images of the front and back of the packaging for Lactaid's Fast Act Chewables, including many of the contested statements and disclaimers, are included as Appendix A to this opinion. See Dkt. 19-1 at 2-3.

those other lactose supplements were less expensive for treating lactose intolerance.” Dkt. 45 ¶ 31. DiCroce cites data from Amazon.com showing that Lactaid sells for \$0.20 per pill, while similar lactase supplements that purportedly do not make disease claims sell for \$0.09 per pill or less. Thus, she asserts that she paid an “unwarranted premium” for Lactaid. Id. ¶ 33.

## **II. Procedural History**

DiCroce filed the initial Complaint on October 12, 2021, and Defendants moved to dismiss. The Court allowed Defendants’ motion and dismissed the action without prejudice on April 8, 2022, finding that the Complaint failed to plead an injury-in-fact sufficient to establish standing. DiCroce promptly filed an Amended Complaint that brings three causes of action: violation of the Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, and other states’ consumer protection statutes (Count I); unjust enrichment (Count II); and false advertising in violation of Mass. Gen. Laws ch. 266, § 91 (Count III). DiCroce brings the Amended Complaint on behalf of the proposed class of persons who purchased Lactaid products and are from states with laws concerning consumer protection, unjust enrichment, and false advertising substantially similar to Massachusetts’s. Defendants again moved to dismiss for failure to state a claim and for lack of standing. The Court heard argument on August 16, 2022.

## DISCUSSION

### I. Legal Standard

To survive a motion to dismiss under Rule 12(b)(6), a complaint must allege "a plausible entitlement to relief." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 559 (2007). "While a complaint attacked by a Rule 12(b)(6) motion does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of a cause of action's elements will not do." Id. at 555 (cleaned up); see also Rodriguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95-96 (1st Cir. 2007). The plausibility standard requires the Court to proceed in two steps. First, the Court must "separate the complaint's factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited)." Morales-Cruz v. Univ. of P.R., 676 F.3d 220, 224 (1st Cir. 2012). The Court must next determine whether the factual allegations permit it "to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (quoting Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009)).

On a motion to dismiss under Rule 12(b)(1), the plaintiff must plead facts sufficient to establish Article III standing. See Hochendoner v. Genzyme Corp., 823 F.3d 724, 730 (1st Cir. 2016). The Court generally looks to whether the allegations in

the complaint establish standing, although the Court may weigh evidence outside of the complaint where the defendant brings a factual challenge. See Laufer v. Acheson Hotels, LLC, 50 F.4th 259, 265 (1st Cir. 2022). The elements of standing are (1) an “injury in fact” which is “concrete and particularized” and “actual or imminent”; (2) a “causal connection between the injury and the conduct complained of”; and (3) a likelihood that the injury will be “redressed by a favorable decision.” Lujan v. Defs. of Wildlife, 504 U.S. 555, 560-61 (1992).

## **II. Analysis**

### **A. Article III Standing**

DiCroce argues that the allegedly misleading Lactaid labels caused her an injury-in-fact because but for those statements, she would not have purchased Lactaid and may have purchased a cheaper alternative.

To satisfy the concreteness and particularization elements of an injury-in-fact, the harm must “actually exist” above and beyond a “bare procedural violation” and must affect the plaintiff “in a personal and individual way.” Hochendoner, 823 F.3d at 731 (quoting Spokeo, Inc. v. Robins, 578 U.S. 330, 339-41 (2016)). The bar for pleading an economic injury is low; “even an ‘identifiable trifle’” suffices. Katz v. Pershing, LLC, 672 F.3d 64, 76 (1st Cir. 2012) (quoting Adams v. Watson, 10 F.3d 915, 924 (1st Cir. 1993)). A consumer who overpays for a product because

of purportedly deceptive conduct by the manufacturer may suffer a legally cognizable injury for Article III purposes. See Gustavsen v. Alcon Labs., Inc., 903 F.3d 1, 7-8 (1st Cir. 2018) (holding plaintiffs adequately alleged an Article III injury by claiming they paid an extra \$500-\$1000 per year for eye drop bottles designed to dispense unnecessarily large drops).

Here, unlike in the initial Complaint, DiCroce has plausibly alleged a legally cognizable injury. She claims to have paid at least \$0.11 per pill more for Lactaid than she would have paid for alternative products because Lactaid made disease claims. DiCroce naturally has a "legally protected interest in [her] own money." Id. at 7. The parties dispute whether Lactaid and the alternatives, Puritan's Pride and Vitamin Shoppe lactase supplements, are equivalent such that the price per pill can be fairly compared. The Court cannot resolve this factual dispute at this stage. It suffices that DiCroce alleges she paid a premium for Lactaid because of its marketing statements.

Defendants point to cases discussing whether a consumer's payment for a product because of deceptive advertising is a legally cognizable injury under Chapter 93A. See, e.g., Shaulis v. Nordstrom, Inc., 865 F.3d 1, 11 (1st Cir. 2017); Tyler v. Michaels Stores, Inc., 984 N.E.2d 737, 745 (Mass. 2013). These cases address a consumer's statutory standing. See Katz, 672 F.3d at 75 ("Article III standing presents a question of justiciability; if



it is lacking, a federal court has no subject matter jurisdiction over the claim . . . . By contrast, statutory standing goes to the merits of the claim.”). The Court here only determines that DiCroce has succeeded in alleging a justiciable case or controversy. Whether the Amended Complaint establishes Chapter 93A standing is a closer question that the Court need not address, as the Amended Complaint fails on the merits on other grounds.

#### **B. Consumer Deception**

To plead a Chapter 93A deceptive trade practices claim, a plaintiff must allege “(1) a deceptive act or practice on the part of the seller; (2) an injury or loss suffered by the consumer; and (3) a causal connection between the seller’s deceptive act or practice and the consumer’s injury.” Tomasella v. Nestlé USA, Inc., 962 F.3d 60, 71 (1st Cir. 2020) (quoting Casavant v. Norwegian Cruise Line, Ltd., 919 N.E.2d 165, 168–69 (Mass. App. Ct. 2009)). “[A]n advertisement is deceptive when it has the capacity to mislead consumers, acting reasonably under the circumstances, to act differently from the way they otherwise would have acted (i.e., to entice a reasonable consumer to purchase the product).” Aspinall v. Philip Morris Cos., Inc., 813 N.E.2d 476, 488 (Mass. 2004). In reviewing allegations of deceptive labeling, the Court looks to “whether the complaint’s allegations make it plausible that, on a full factual record, a factfinder could reasonably regard the label as having the capacity to mislead.”

Dumont v. Reily Foods Co., 934 F.3d 35, 40 (1st Cir. 2019). This standard “depends on the likely reaction of a reasonable consumer rather than an ignoramus.” Aspinall, 919 N.E.2d at 487.

Similarly, a false advertising claim under Mass. Gen. Laws ch. 266, § 91 requires a showing that the defendant disseminated an advertisement which “contains any assertion, representation or statement of fact which is untrue, deceptive or misleading.”

Here, no reasonable consumer could find Lactaid’s product labels deceptive, nor has DiCroce identified a misrepresentation of fact. Her primary claim is that a consumer reading a Lactaid label would be misled by Defendants (1) marketing of Lactaid as a supplement even though they (2) make claims on Lactaid’s packaging suggesting that it is a drug while (3) also stating that Lactaid is not a drug and cannot treat a disease. Contrary to DiCroce’s position, Lactaid’s packaging is not misleading. As noted, the labels that DiCroce attaches to the Amended Complaint each plainly state that Lactaid is not a drug and is not intended to treat any disease. See Dkt. 45-1; Dkt. 45-2; Dkt. 45-3. Courts “routinely conclude that the presence of a disclaimer, considered in context, precludes the finding that a reasonable consumer would be deceived by the defendant’s conduct.” Bowring v. Sapporo U.S.A., Inc., 234 F. Supp. 3d 386, 390 (E.D.N.Y. 2017). Lactaid’s disclaimers are conspicuously located on the front and back of each box. The statement that Lactaid is not a drug is in bold on the back. Any

reasonable consumer reading Lactaid's label would conclude that Lactaid is a supplement that assists with the digestion of dairy and is not a drug that can treat a disease.

DiCroce advances the alternative argument that the disclaimers on Lactaid's labels misled her because they falsely imply that Lactaid's packaging does not require FDA evaluation. This conclusory allegation does not accord with the language of the disclaimers, which say only that statements about Lactaid have not been evaluated by the FDA. See Fitzgerald v. Polar Corp., No. 20-cv-10877, 2020 WL 6586628, at \*5 (D. Mass. Nov. 10, 2020). Further, whether Lactaid's label statements require FDA evaluation would not influence a reasonable consumer's purchasing decision where the product's label discloses that they are not FDA-approved. DiCroce's claims therefore fail.

**ORDER**

For the foregoing reasons, Defendants' motion to dismiss (Dkt. 50) is **ALLOWED**. The Amended Complaint is dismissed with prejudice.

/s/ PATTI B. SARIS  
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Hon. Patti B. Saris  
United States District Judge